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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,670	02/09/2004	Ramez Emile Nicola Shehada	064693-0097	1453

7590 02/01/2007  
MCDERMOTT, WILL & EMERY  
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EXAMINER
HILL, LAURA C

ART UNIT	PAPER NUMBER
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.



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APPLICATION NO/ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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10-775-670

EXAMINER
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ART UNIT	PAPER
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20070129

DATE MAILED:

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner for Patents**

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/775,670	NECOLA SHEHADA, RAMEZ EMILE	
	Examiner	Art Unit	
	Laura C. Hill	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments filed 18 January 2007 have been fully considered but they are not persuasive.

1. In response to Applicant's arguments that neither Johnson nor Polanyi discloses the Applicant's surgical drain having an optical fiber, wherein the first optical fiber distal end branches away from the conduit and is configured for insertion into the tissue (see Remarks pages 5-6, Examiner maintains that Polanyi discloses light-conducting fibers 18 having a relatively sharp right-angular bend/branching away from the conduit (column 2, lines 3-7, figure 3) for adequate spacing of the catheter walls within the patient (column 2, lines 60-63). The Claim 1 recitation of "the distal end branches away from the conduit" (lines 7-8) does not exclude the interpretation that the distal end of the "first optical fiber" is embedded or located within the elongated conduit. So long as the "first optical fiber" component "branches away" or bends from an axis located in the elongate conduit, the claim limitation has been met. Support for this interpretation is found on page 11, lines 1-5 and figure 2B of the instant specification which recites the "surgical drain 10 *may* have a plurality of drain branches 10a/b to accommodate monitoring larger wounds...". It is noted that in the figures submitted by Applicant, the branches 10a/b are shown as deviating from the horizontal transverse axis that forms elongate conduit 42. As defined by Applicant the elongate conduit 42 that comprises the surgical drain 10 is not limited to being a separately distinct element but rather may comprise a unitary structure from which the optical fibers extend as seen in figure 2B.

Thus a prima facie case has been met since Polanyl discloses branching away fibers as discussed above. Furthermore, it is important to note that Johnson also discloses light-conducting fibers 33 which are *tapered/branch* away from the catheter conduit 30 (column 3, lines 25-35, figure 7).

***Information Disclosure Statement***

2. The information disclosure statement filed 18 January 2007 fails to comply with 37 CFR 1.97(c) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.

***Claim Objections***

3. All objections to the claims have been removed in view of Applicant's remarks and amendments submitted 18 January 2007.

***Claim Rejections - 35 USC § 112***

4. All rejections to the claims under 35 USC 112, 1<sup>st</sup> paragraph have been removed in view of Applicant's remarks and amendments submitted 18 January 2007.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-6, 8-9 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 3,866,599) in view of Polanyl (US 3,674,013). In regard to claim 1 Johnson discloses an implantable surgical drain 1 comprising an elongated conduit 2 configured to be implanted in and to drain from a body cavity (column 1, lines 7-10, column 2, lines 12-28); the drain further comprises a first optical fiber 11, 21, 27

and a second optical fiber 11, 21, 27; the fibers are configured to transmit and receive energy from body tissue (column 1, lines 20-25 and lines 44-49, column 2, lines 12-22 and lines 51-66). Johnson discloses multiple optical fibers, any of which may be considered a first optical fiber and a second optical fiber. Johnson does not expressly disclose that the first distal end of the first optical fiber branches from the conduit.

**Polanyi** teaches a fiber optic catheter 10 implanted into the body (column 1, lines 1-59, column 2, lines 54-63) with light emitting and light receiving optical fibers 18 (column 1, line 73-column 2, line 7), said fibers 18 are directed at an angle to one side of the catheter wall so that the optical fiber remains spaced from the body organs and as a result, this reduces the chance of unreliable or false readings from the body organ or cavity (column 2, lines 49-63, figure 3). One would be motivated to modify the distal branch end of the first optical fiber of Johnson with the branching optical fiber of Polanyi since having the fiber bend away from the conduit allows the fiber to remain spaced from the body organ, thereby reducing the likelihood of inaccurate readings from the body cavity since the references are in the same field of endeavor; implantable catheters with fibers for obtaining physiological properties. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the distal end of the first optical fiber, thus providing a branched fiber with accurate readings.

In regard to claim 2 Johnson discloses the optical fibers 11,21,27 extend substantially parallel to each other; thus the distal ends of the optical fibers are substantially parallel to each other (figures 2-3 and 6).

In regard to claim 3 Johnson discloses the distal ends of the optical fibers are configured for insertion into tissue (column 2, lines 29-50).

In regard to claim 4 Polanyi discloses a housing/collar 8 extending inwardly from the conduit supporting the fibers 18 for insertion into a body (column 2, lines 17-23, figure 3).

In regard to claims 5-6 Johnson discloses that the drain comprising a sensing system that can sense physiological properties, including oxygenation and pressure (column 1, lines 44-49, column 2, lines 16-22 and 33-36).

In regard to claim 8 Johnson discloses the fibers embedded within the conduit (all figures, columns 3, lines 6-9).

In regard to claim 9 Johnson discloses the drain further comprises an oximeter that receives energy from the optical fibers 11, 21, 27 (column 2, line 62-column 3, line 5). The oximeter provides measurements so it would inherently have to display these measurements in some form to the user. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not expressly disclose not render the old composition patentably new to the discoverer. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

In regard to claim 12 Johnson discloses the optical fibers 11, 21, 27 includes a component such as a surface or a distal end of any other portion of the fiber itself affixed to conduit 2 (figures 2-6, column 3, lines 6-9).

In regard to claim 13 see the discussion above with respect to claims 8 and 12.

In regard to claim 14 see the discussion above with respect to claims 5-6.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of Polanyl as applied to claims 1-6 and 8-14 above, and further in view of Russo et al. (US 4,317,452). Johnson/Polanyl disclose the article as discussed above with respect to claim 1 but do not expressly disclose the conduit comprises a plurality of holes spaced along substantially the entire length of the drain portion. **Russo** discloses a surgical drain comprising an implantable conduit 10 (column 3, lines 26-30) having a plurality of holes along substantially the entire length of the drain portion which allows body fluids in the cavity to pass into and along the conduit into a drainage site (figure 1, column 2, lines 7-19, column 4, line 56-column 5, line 2). One would be motivated to modify Johnson/Polanyl with the plurality of holes as taught by Russo to affect the manner in which fluid passes and flows into the tube since the references are in the same field of endeavor; implantable conduits. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the catheters thus providing drainage holes.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



Art Unit: 3761

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (hours vary).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura C. Hill  
Examiner  
Art Unit 3761

LCH



TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

